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| EXAMINER | |
|---|---|
| COUNTS, GARY W | |

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| 1641 | |

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/887,871 | AMIRKHANIAN, VAROUJ | |
| | Examiner | Art Unit | |
| | Gary W. Counts | 1641 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *32-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24, and 26-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Status of the claims

The amendment filed April 23, 2004 is acknowledged and has been entered.

Note: The listing of claims filed April 23, 2004 shows that claim 31 has been withdrawn. However, the claim was rejected in a previous office action and is rejected in this office action (see below). It is unclear if this was a typo or if applicant intended to cancel claim 31. Therefore, Examiner has addressed claim 31 as if it were still part of the rejected claims.

### *Specification*

The amendment filed April 23, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: On page 16, lines 18 to page 17 line 5 of the specification. The disclosure (i.e., as shown in Fig. 2B, a transition in width from the width of the separation channel 504 to the width of the collar 10). The applicant has not defined the term transition and from the figures has not clearly disclosed where a transition would begin and end.

Applicant is required to cancel the new matter in the reply to this Office Action.

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 and 26-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The applicant discloses that the zone for optical detection of sample components is located at a widened zone along the separation channel. And that the widened detection zone is a micro-bore collar having a micro-channel that coaxially surrounds the exit of a capillary column that defines a capillary channel. On pages 16, line 18 – page 17, line 5 in the specification. The applicant discloses that as the analytes flow from the separation channel 504 of capillary column 22 into the collar 10, the analytes remain subject to the applied potential. As a result, the analytes continue to maintain separation state as they migrate/flow past the detection zone 20. Some mixing or diffusion of the analytes may occur in the collar near the exit of the separation channel 504, but analytes "regroup" into separated state as they continue down along the collar 10 towards the detection zone 20. The detection zone 20 is preferably located at 100 x 500 ID of the collar, more like 225 times ID, to provide sufficient distance for the analytes to regroup before detection at the detection channel 504, the analyte bands are narrower in the axial direction. Thus the detection resolution may be improved as a result. The only specific disclosure of a transition occurs on page 1, lines 20-21 in the specification which discloses that bioanalysis, such as DNA analysis, is rapidly making the transition from a purely scientific quest for accuracy to a routine procedure with increased, proven

dependability. The applicant does not disclose a transition in width from the first width of the separation channel to the second width of the detection section. There is no description in the specification disclosing a transition from the first width of the separation channel to the second width of the detection section.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-24 and 26-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 5 and 9 "a transition" is vague and indefinite. It is unclear what applicant is referring to. There is no definition provided for the term in the specification. See also deficiencies found in claim 30.

Claim 1 is vague and indefinite because it is unclear where this first width of the separation channel is located. It is located at the exit or entrance? And if it is the exit, at what point of the exit, the inside of the separation channel or the outside of the separation channel (see Fig. 2B)?

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-5, 7, 26, 27, and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (Axial-Beam Laser Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744) in view of Yin et al (US 5,650,846).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Taylor et al differs from the instant invention in failing to teach the separation channel and a transition in width from the first width of the separation channel to the

second width of the detection section. Taylor et also fails to teach the location being defined at a distance of 100 to 500 times the second with of the detection section from the transition.

Yin et al disclose a microcolumnar separation device (col 4, lines 20-67). Yin et al disclose that this microcolumn separation device can be a capillary electrophoresis channel (separation channel) (col 4). Yin et al disclose that the separation channel comprises a detection zone (Fig. 8, items 18, 124 139, 130 and 128, the detection region extends from item 18 to item 130). Yin et al disclose that the separation channel comprises a flare located at the end of the separation channel (col 7, line 48 – column 8, line 9). Yin et al disclose that detection zone has an enlarged opening to the lumen of the separation channel for receiving the optical fiber. Yin et al disclose that detection zone provides the alignment and nonfixed confinement of optical fiber to the separation channel.

It would have been obvious to one of ordinary skill in the art to incorporate a detection zone as taught by Yin et al into the device of Taylor et al because Yin et al shows that this detection zone provides the alignment and nonfixed confinement of optical fiber to the microcolumn.

With respect to the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition as recited in the instant claims, the optimum distance of the second width from the transition can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover

an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

8. Claims 1-5, 7, 26, 27 and 29-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al (Axial-Beam Laser-Excited Fluorescence Detection in Capillary Electrophoresis, Anal. Chem. 1992, Vol. 64, 1741-1744) in view of Zhu et al (US 5,763,277).

Taylor et al disclose a detection system for axial-beam laser excited fluorescence detection in capillary electrophoresis. Taylor et al disclose the use of a fiber optic which focuses the excitation laser beam which directs the light along the capillary rather than across it (col 1, page 1741, lines 1-27). Taylor et al also disclose that this fiber is directed into an end of the detection section in proximity to the detection zone (col 1, page 1742, lines 8-10). Taylor et al also disclose the use of cladding material and a jacket which surround the fiber for guiding the excitation radiation from the excitation source to the detection zone (col 2, page 1741, lines 12-18). Taylor et al also disclose a means for detecting radiation emission from the detection zone (col 1, page 1742, lines 22-39).

Taylor et al differs from the instant invention in failing to teach the separation channel and a transition in width from the first width of the separation channel to the second width of the detection section. Taylor et also fails to teach the location being defined at a distance of 100 to 500 times the second with of the detection section from the transition.

Zhu et al disclose a detection system which comprises a capillary tube (col 6, line 46) used for electrophoresis (separation channel) (col 2, lines 49-51) which defines a detection zone. Zhu et al also disclose that the inner diameter of the axially oriented system component is increased at the location of contained axially oriented fiber optic means (col 5, lines 1-3). Zhu et al disclose that the increased diameter provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic (col 6, lines 15-21).

It would have been obvious to one of ordinary skill in the art to incorporate a separation channel and detection zone has taught by Zhu et al into the device of Taylor et al because Zhu et al shows that this separation channel and detection zone provides a non-constricted annular space in which sample analyte containing sample solution can flow, in the presence of the fiber optic.

With respect to the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition as recited in the instant claims, the optimum distance of the second width from the transition can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Further, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover

an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454,456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation ." Id. At 458,105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272,276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

9. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 26, 27 and 29-31 above, and further in view of Liu et al (US 5,416,879).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al Zhu et al differ from the instant invention in failing to teach the tube is made of Teflon and the light transmitting material comprises a gel.

Liu et al disclose Teflon fluoropolymer capillary tubing which has a refractive index in the range of approximately 1.29 to 1.31 (col 4, lines 18-21). This Teflon tubing allows for the channeling light through a light conducting core region which is surrounded or clad by the Teflon fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber (col 3, lines 50-55).

It would have been obvious to one of ordinary skill in the art to incorporate the use of the Teflon fluoropolymer as taught by Liu et al into the modified detection system of Taylor et al because Liu et al shows that this Teflon tubing allows for the channeling

of light through a light conducting core region which is surrounded or clad by the Teflon fluoropolymer which has a lower refractive index to the light than the material comprising the core and thus allows the propagation of light with negligible losses through an optical fiber.

With respect to the light transmitting material comprising a gel Taylor et al teaches the insertion of the fiber (light transmitting material) into the separation channel (comprised of the gel), thus the light transmitting material comprises a gel.

10. Claims 9-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 26, 27 and 29-31 above, and further in view of Hazman et al (US 5,625,403).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al and Zhu et al differ from the instant invention in failing to teach introducing excitation radiation from at least two radiation sources providing radiation at different wavelengths. Taylor et al and Zhu et al also fail to teach the use of a beam splitter.

Hazman et al disclose the use of multiple diode lasers (radiation sources), each of which emits a source beam of light of different wavelengths (see abstract). Hazman et al also disclose an optical element that channels the radiation from the different radiation sources. Hazman et al also disclose the use of a beam splitter (see figure 2). The use of the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head (col 2, lines 27-36).

It would have been obvious to one of ordinary skill in the art to incorporate the use of radiation sources, an optical element and a beam splitter as taught by Hazman et al into the modified detection system of Taylor et al because Hazman et al shows that the use of the radiation sources, optical element and beam splitter provides a method of recording on an optically-sensitive medium and enables the realization of a practical high power optical head

11. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al and Hazman et alas applied to claims 1-5, 7, 9-14, 26, 27 and 29-31 above, and further in view of Amirkhanian et al (US 6,184,990).

See above for teachings of Taylor et al., Zhu et al. and Hazman et al.

Taylor et al., Zhu et al., and Hazman et al differ from the instant invention in failing to disclose a means of introducing excitation radiation comprising two fibers directed at the detection zone, wherein each fiber is coupled to one radiation source.

Amirkhanian et al disclose the use of two optical fibers that are utilized for delivery of the excitation from two or more different sources. This arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

It would have been obvious to one of ordinary skill in the art to incorporate the use of two optical fibers as taught by Amirkhanian et al into the modified detection system of Taylor et al because Amirkhanian et al shows that this arrangement enables multiple fluorescence species in the same sample to be excited at the same time for simultaneous detection.

12. Claims 16-18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Yin et al as applied to claims 1-5, 7, 26, 27 and 29-31 above, and further in view of Letcher et al (US 6,326,213) or Liu et al (US 5,444,807).

See above for teachings of Taylor et al and Yin et al.

Taylor et al and Yin et al differ from the instant invention in failing to teach the means for axially detecting radiation emission shares the same single fiber as the means for introducing excitation radiation axially to transmit excitation radiation and radiation emission.

Letcher et al disclose a single step-tapered fiber used for excitation and detection (col 3, lines 1 and 2, see also abstract). The use of this fiber allows for enhancement of the sensitivity of a fiber-optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

Liu et al (US 5,444,807) disclose a single fiber optic for both axial light input to and output from flow through detectors (abstract and col 6, lines 44-60). Liu et al disclose that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis (col 4, lines 36-50).

It would have been obvious to one of ordinary skill in the art to incorporate the fiber of Letcher et al into the modified detection system of Taylor et al because Letcher et al shows that the use of this fiber allows for enhancement of the sensitivity of a fiber-

optic biosensor using fluorescent immunoassay techniques for the rapid detection of an analyte.

It also would have been obvious to one of ordinary skill in the art to incorporate the fiber optic of Liu et al into the modified detection system of Taylor et al because Liu et al shows that this provides for a novel technique by which light absorption and fluorescence may be used as measures of properties of small amounts of a flowing fluid analyte, particularly in conjunction with liquid chromatography and capillary electrophoresis.

13. Claims 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Yin et al and Liu et al (US 5,444,807) as applied to claims 1-5, 7, 16-18 and 26-31 above, and further in view of Hazman et al (US 5,625,403).

See above for teachings of Taylor et al, Yin et al. and Liu et al.

Taylor et al., Yin et al., and Liu et al differ from the instant invention in failing to disclose a confocal optical element that transmits excitation radiation and radiation emission.

Hazman et al disclose the use of a dichroic beam combiner along with a set of lens. This dichroic beam combiner is used to selectively reflect and transmit light according to its wavelength (col 4, lines 30-33). The use of the beam combiner and set of lens allows for the combination of laser beams and enabling the realization of a practical high power optical head.

It would have been obvious to one or ordinary skill in the art to incorporate the beam combiner and set of lens as taught by Hazman et al into the modified detection

system of Taylor et al because Hazman et al shows that the use of the beam combiner allows for selectivity of light reflection and transmission according to its wavelength and the beam combiner and set of lens also allows for the combination of laser beams and enabling the realization of a practical high power optical head.

14. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al in view of Zhu et al as applied to claims 1-5, 7, 25-27 and 29-31 above, and further in view of Pentoney, Jr. et al (US 5,675,155).

See above for teachings of Taylor et al and Zhu et al.

Taylor et al and Zhu et al differ from the instant invention in failing to teach the use of a parabolic reflective collector.

Pentoney, Jr. et al disclose the use of a high collection efficiency parabolic reflector (col 5, lines 14-39). The use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector (col 2, lines 24-32).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a parabolic reflector as taught by Pentoney, Jr. et al into the modified detection system of Taylor et al because Pentoney, Jr. et al shows that the use of this parabolic reflector allows for an economical highly sensitive, stable and rugged detection system for use in connection with high throughput separation systems and also allows for multiple excitation wavelengths and detecting multiple emission wavelengths using a single detector.

***Double Patenting***

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1, 3-5, 29 and 30 are rejected under the judicially created doctrine of double patenting over claims 1-19 of U. S. Patent No. 6,529,275 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Both the instant application and US Patent 6,529,275 claim a detection system for a bio-separation device a detection section and a separation channel having a transition in width from a first width to a second width, the detection section defining a detection zone at a distance of 100 to 500 times the second width from the transition; means for introducing excitation and means for axially detecting radiation emission and introducing axial excitation.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of

the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

***Response to Arguments***

17. Applicant's arguments filed April 23, 2004 have been fully considered but they are not persuasive.

Applicant argues that the amendment to the specification does not introduce new matter, as supported by Figure 2B and that Figure 2B defines a transition in the width from the width of the separation channel 504 to the width of the collar 10. This is not found persuasive because Figure 2B does not clearly define a transition. For example, where is the transition occurring at the exit of the separation channel? The exact point of exit, just outside the exit, the inner point of the exit of the capillary column, the outer point of exit of the capillary column? The applicant has not clearly defined a transition and therefore the amendment introduces new matter.

Applicant further argues that related patent application serial no. 09/887,872 had issued as U.S. Patent No. 6,529,275, which claims also employ this "transition" recitation based on essentially a similar disclosure with respect to this structure. And that while individual applications should be reviewed and examined on its own merits with respect to prior art, to fine the use of similar recitation of "transition" in the present application to be unsupported by the original specification would be inconsistent and arbitrary discretion of the Examiners. This is not found persuasive because Examiner is relying on the original disclosure of the current application being reviewed. The

Examiner is not relying on a similar disclosure or any other disclosure. The current application does not clearly define "a transition" and therefore the amendment to the claims and the specification is considered new matter and thus the rejection is maintained.

Applicant argues that Taylor does not disclose the capillary having a widened section at the detection zone, but rather a capillary having a uniform width along its length, even at the detection zone and that Zhu does not make up for the deficiencies of Taylor. Applicant argues that Zhu is silent as to the location of the detection zone, much less disclose defining the detection zone to be at such a distance from the transition. Examiner agrees that Zhu does not specifically define the detection zone and that the detection zone be located at a distance 100-500 time the second width of the detection section from the transition. However, Zhu et al does teach the concept that the fiber optic is positioned in a widened section of the separation channel and hat the fiber optic is placed at a distance from the transition point and as stated above, the optimum distance can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art. Applicant further argues that Zhu did not address the concern with mixing and diffusion and regrouping of analyte back into separated state and that the present invention enables improved detection of the separated analytes, by taking into consideration of effects of mixing, diffusion and regrouping. Such consideration and benefits need not be recited in the claims, since the limitation of the specific location of the detection zone would allow such benefits to be accomplished. This is not found persuasive because since one of ordinary skill in

the art would vary the distance of the detection zone for optimization purposes, the varied distance would provide the benefits of mixing, diffusion and regrouping of the analyte.

Applicant further argues that there is no motivation to combine Taylor and Zhu because Taylor discloses use of a fiber optic for axial excitation and that Zhu teaches use of a fiber optic for axial detection. This is not found persuasive because Examiner has not relied upon Zhu for the teaching of axial excitation or axial detection, rather the Examiner has relied upon Zhu et al for teaching that it is known in the art that the fiber optic can be positioned in a widened section of the separation channel and for the advantages of having the fiber optic in a widened section of the separation channel.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

NOTE: The applicant failed to address the 103 rejections concerning Taylor et al in view of Yin et al. presented in the previous office action.

***Conclusion***

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary Counts
Examiner
Art Unit 1641
May 13, 2004

LONG V. LE
SUPERVISORY PATENT EXAMINER
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05/14/04